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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,432	03/17/2004	Ulrich Certa	21574	4051

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HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER
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BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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05/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/802,432

Applicant(s)

CERTA ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 12, 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/22/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claim 6 was not properly amended in accordance with the rules of 37 CFR 1.121 because the deletion and insertion of the claim dependency was not indicated by lining through and underlining. For the purpose of examination the claim has been interpreted as amending its dependency from claim 5 to claim 1.

2. All previous rejections and objections made in the Office action mailed 22 September 2006 have been withdrawn as noted below. In view of the species requirement made in the Office action mailed 22 September 2006, the applicants are requested to acknowledge their telephonic election of the interferon (IFN) species of protein as noted in the Office action mailed 22 September 2006. Because the interferon species of protein in Markush type claims 7 and 13 have been found to be allowable, examination has been extended to the erythropoietin (EPO) species of protein. New grounds of rejection have been made regarding the EPO species of protein.

### ***Claim Objections***

3. The objection to claims 7, 12, and 13 in the Office action mailed 2 September 2006 is withdrawn in view of the amendment filed 22 February 2007.

### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 9-13 under 35 U.S.C. 112, second paragraph in the Office action mailed 2 September 2006 is withdrawn in view of the amendment filed 22 February 2007.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 7 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of analyzing the effect of pegylated EPO on the level of expression of SEQ ID NOS: 1-29. The specification mentions EPO on page 6, line 2 without discussing what sequences have their level of expression affected by EPO treatment. The specification describes SEQ ID NOS: 1-29 as being affected by IFN treatment in Table 3, pages 29-30.

7. Claims 1-3, 6, 7, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pegylated interferon does not reasonably provide enablement for pegylated proteins other than interferon, such as EPO. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

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a) The quantity of experimentation necessary: In order to practice the claimed invention one of skill in the art must use pegylated proteins other than IFN such as EPO by measuring the effect of exposure to the protein on expression of SEQ ID NOS: 1-29. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the full scope of the claimed invention.

b) The amount of direction or guidance presented: The specification presents guidance in Table 3 that expression levels of SEQ ID NOS: 1-29 are affected by IFN treatment. The specification does not show that expression levels of SEQ ID NOS: 1-29 are affected by any other protein.

c) The presence of absence of working examples: The specification does not present working examples of a protein other than IFN that affects the expression levels of SEQ ID NOS: 1-29. The specification does not present working examples of pegylation of EPO, a preferred embodiment of claims 7 and 13, or of any other protein.

d) The nature of the invention, gene expression analysis, is complex.

e) The state of the prior art: Komor et al. (published 2 years after the effective filing date of the instant application) shows a number of genes whose expression level was observed to be modulated by treatment of cells with EPO. Komor et al. shows in Table 2 genes that were observed to be modulated by EPO treatment. None of the genes that were affected by EPO treatment are among the genes related to SEQ ID NOS: 1-29.

A search of the prior art did not show pegylated EPO, a preferred embodiment of claims 7 and 13.

f) The relative skill of those in the art is high.

g) The predictability of the art: The prior art does not predict use of the claimed method for proteins other than IFN.

h) The breadth of the claims: The claims are broad in that they embrace embodiments not enabled by the specification.

A skilled practitioner would first turn to the specification for guidance and working examples to practice the full scope of the claimed invention. However the specification only enables use of pegylated IFN in the claimed method. The skilled practitioner would next turn to the prior art for such guidance, but the prior art does not provide such guidance. Finally, said practitioner would turn to trial and error experimentation to practice the claimed method of using pegylated proteins other than IFN to modulate levels of SEQ IDS NOS: 1-29 without assurance of success. Such represent undue experimentation.

***Claim Rejections - 35 USC § 102***

8. The rejection of claims 1-3 under 35 U.S.C. 102(b) in the Office action mailed 2 September 2006 is withdrawn in view of the amendment filed 22 February 2007.

***Claim Rejections - 35 USC § 103***

9. The rejections of claims 1, 4-13 under 35 U.S.C. 103(a) in the Office action mailed 2 September 2006 is withdrawn in view of the amendment filed 22 February 2007.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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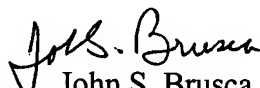
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 12 May 2007  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb